

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**5403. Mediatric (estrone) capsules, pentaerythritol tetranitrate tablets, and diphenmethanil methylsulfate tablets.** (F. D. C. No. 40220. S. Nos. 62-528 M, 62-530/2 M.)

**QUANTITY:** 1 300-capsule btl. of *Mediatric (estrone) capsules*, 1 3,500-tablet btl. and 1 1,500-tablet btl. of *pentaerythritol tetranitrate tablets* and 1 250-tablet btl. of *diphenmethanil methylsulfate tablets* at New York, N. Y.

**SHIPPED:** On unknown dates, from Detroit, Mich., Cleveland, Ohio, and Morris Plains and Bloomfield, N. J.

**LIBELED:** 5-29-57, S. Dist. N. Y.

**CHARGE:** *Mediatric capsules.* 502 (b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502 (e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

*Pentaerythritol tetranitrate tablets.* 503 (b) (4)—the article was a drug subject to 503 (b) (1); and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*Diphenmethanil methylsulfate tablets.* 502 (d)—the article contained a chemical derivative of barbituric acid (phenobarbital); and, while held for sale, the label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

**DISPOSITION:** 7-16-57. Default—destruction.

**5404. Botanical Medicine.** (F. D. C. No. 39316. S. No. 27-771 M.)

**QUANTITY:** 302 16-oz. btls. and 67 32-oz. btls. at Tampa, Fla., in the possession of M. M. Moran.

**SHIPPED:** Between 3-29-56 and 9-29-56, from Cincinnati, Ohio.

**LABEL IN PART:** (Btl.) "Chief Whahoo Brand Botanical Medicine \* \* \*  
Active Laxative Ingredients: Buckthorn, Senna, Cascara Sagrada and Aloe.  
Inactive Ingredients: Ginger, Calamus, Anise, Licorice, Mandrake, Methyl Salicylate, Salicylic and Benzoic Acid, Iron and Ammonium Citrate, Saccharin Soluble, Cassia and Spearmint Oil, Whahoo, Butternut, Uva Ursi, Sarsaparilla, Colocynth, Buchu, Juniper Berries and Wild Cherry."

**ACCOMPANYING LABELING:** Circulars designated "Your Digestive System."

**RESULTS OF INVESTIGATION:** The circulars were printed locally on order of the consignee and were used by the consignee, together with oral statements, to promote the sale of the article.

**LIBELED:** 8-6-56, S. Dist. Fla.; amended libel on or about 10-30-56.

**CHARGE:** 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for headache, dizziness, sour stomach, coated tongue, bad breath, skin eruptions, loss of appetite, indigestion, and sickness generally; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in purifying the blood and removing poisons from the liver, kidneys, bowels, stomach, and blood stream, which were the conditions and purposes for

\*See also No. 5402.

which the article was intended and for which it was offered orally by the consignee to prospective purchasers.

DISPOSITION: 9-12-58. Default—destruction.

**5405. Oza Compound.** (F. D. C. No. 39849. S. No. 59-960 M.)

QUANTITY: 15 cases, 4 1-gal. jugs each, at Tampico, Ill.

SHIPPED: 11-28-56, from Fort Wayne, Ind., by Oza Compound Products.

LABEL IN PART: (Jug) "OZA \* \* \* Formula: Active Ingredients: Alum, Oak Bark, Rosin, Sodium Benzoate Oza Compound \* \* \* Use as a general tonic \* \* \* Directions: Children, up to 5 years, 1 tablespoonful, 5 to 10 years, 2 tablespoonsful, 10 to 15 years, 3 tablespoonsful. Adults, 4 tablespoonsful, after each meal."

LIBELED: 1-29-57, N. Dist. Ill.

CHARGE: 502 (a)—when shipped, the label of the article bore the statement "Use as a general tonic," which statement was false and misleading since the article was not a tonic; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, and, because of its unscientific formula, it was not feasible to devise directions under which the layman could use the article to accomplish the purposes for which it was intended.

DISPOSITION: Willard Smith, t/a Oza Compound Products, appeared as claimant; and, on 3-15-57, upon stipulation of the parties, an order was entered directing that the case be transferred to the Southern District of Indiana. Interrogatories were served upon, and answered by, the claimant.

On 5-8-58, a consent decree of condemnation was entered; and, on 5-14-58, the article was ordered destroyed.

**5406. Ovacide.** (F. D. C. No. 40221. S. No. 66-334 M.)

QUANTITY: 17 6-oz. jars and 2 12-oz. jars and 1 drum containing 20 lbs. at Oakland, Calif.

SHIPPED: 2-22-56, from Portland, Oreg.

LABEL IN PART: (Jar) "Ovacide \* \* \* Antiseptic Powder."

LIBELED: 5-24-57, N. Dist. Calif.

CHARGE: 502 (a)—while held for sale, the name "Ovacide" and certain statements on the jar label represented and suggested that the article was antiseptic under conditions of use and was an adequate and effective treatment for all vaginal infections and inflamed catarrhal conditions of the mucous membranes, which name and statements were false and misleading since the article was not antiseptic under conditions of use and was not an adequate and effective treatment for the conditions represented; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since the directions failed to specify that the article should not be used more than twice weekly for cleansing purposes only, unless otherwise directed by a physician.

DISPOSITION: 6-11-57. Default—destruction.

**5407. Head harness device.** (F. D. C. No. 40214. S. No. 72-962 M.)

QUANTITY: 15 devices at Salt Lake City, Utah.

SHIPPED: 3-27-57, from Idaho Falls, Idaho, by Clifford Thiede.